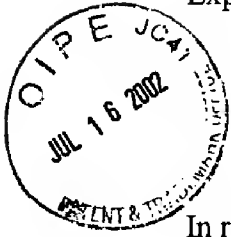


Express Mail Label No. EV 093387704 US



Attorney Docket No. GC22.4-CON

In re application of: Rasmussen et al.

Application No.: 09/995,337

Filed: November 27, 2001

Examiner: Not Yet Assigned

Group No.: 1652

For: ENZYMATICALLY ACTIVE RECOMBINANT  
GLUCOCEREBROSIDASE

Assistant Commissioner for Patents  
Box: Missing Parts  
Washington, D.C. 20231

Response to Notice to File Missing Parts of Nonprovisional Application

Sir:

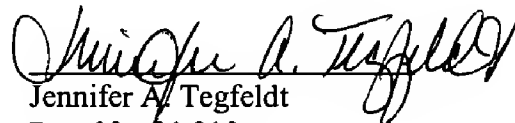
In response to the Notice to File Missing Parts of Nonprovisional Application dated December 17, 2001, the time for response to which having been extended by the filing of a Petition for Extension of Time and payment of the appropriate fee, to and including July 17, 2002, Applicants respectfully submit the following:

1. A copy of the Notice to File Missing Parts of Nonprovisional Application dated December 17, 2001.
2. A Petition for Extension of Time under 37 CFR 1.136(a), with authorization of payment from deposit account.

3. A copy of the signed Combined Declaration and Power of Attorneys filed in U.S. Patent Application Serial Nos. 07/289,589 filed December 23, 1988, and 07/455,507 filed December 22, 1989, on which priority is claimed for the above-noted patent application.
4. A substitute copy of the application having pages 1-35 (including 28 pages of specification, 6 pages of claims, and 1 page of Abstract), which complies with the size requirements of 36 CFR 1.52. No new matter has been added.
5. A substitute copy of the drawings as originally filed in parent application Serial No. 07/455,507. Kindly note that these drawings are the same as those drawings filed in parent application Serial No. 08/015,735, which were included in the copy of the above-captioned application as filed. No new matter has been added.
6. A copy of each of the cell culture deposit certificates having ATCC Designations 67866 and 68194, are submitted herewith. These deposit certificates were made of record in the parent applications, including U.S. Patent No. 5,236,838, from which priority is claimed for this application. Applicants respectfully submit that in view of these deposits, a sequence listing under 37 CFR 1.821-1.825 is not required. These deposits are discussed in the specification as filed at page 27, lines 14-31. No new matter has been added.
7. A Request for Corrected Filing Receipt

Inasmuch as it is believed that Applicants have fully complied with the requirements set forth in the above-identified Notice, favorable consideration of this application is respectfully requested. The Commissioner is further requested to issue a Corrected Filing Receipt, pursuant to the Request submitted herewith.

Respectfully submitted,



Jennifer A. Tegfeldt  
Reg. No. 31,310  
GENZYME CORPORATION  
One Kendall Square  
Cambridge, MA 02139  
(617) 374-7219  
Fax: (617) 252-7977

Express Mail Label No. EV 093387704 US



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/995,337	11/27/2001	James Rasmussen	GC22.4-CON

CONFIRMATION NO. 1762

## FORMALITIES LETTER



Jennifer A. Tegfeldt, Esq.  
GENZYME CORPORATION  
One Kendall Square  
Cambridge, MA 02139

Date Mailed: 12/17/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted*

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is \$ 130.**

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52 because:
  - The specification cannot be scanned or properly stored. Page(s)

07/22/2002 RMEBRAHT 00000010 071074 0995337 1 to 35 do not comply with the size requirements (8 1/2 by 11 inches or 21.0 by 29.7 cm). *The drawings filed are unacceptable because:*  
01 FC:105 130.00 CH *Replacement page(s), together with a statement that the replacement page(s) contain no new matter, are required.*

- This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer

readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

**For questions regarding compliance to these requirements, please contact:**

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or [patin3help@uspto.gov](mailto:patin3help@uspto.gov)

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*A copy of this notice **MUST** be returned with the reply.*

*BS*

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Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

07/17/02

Receipt #3



Express Mail Label No. EV 093387704 US

Practitioner's Docket No. GC22.4CON

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rasmussen et al.

Application No.: 09 / 995,337 Group No.: 1652

Filed: November 27, 2001 Examiner: Not Yet Assigned

For: Enzymatically active recombinant glucocerebrosidase

Assistant Commissioner for Patents  
Washington, D.C. 20231

REQUEST FOR CORRECTED FILING RECEIPT

1. Attached is a copy of the official filing receipt received from the PTO in the above application for which issuance of a corrected filing receipt is respectfully requested.

NOTE: The PTO will not correct the filing receipt until the application is complete (in other words, the applicant files a response to the notice to file missing parts).

2. There is an error with respect to the following data, which is:

☒ incorrectly entered

and/or

☐ omitted.

Error in

- 1. ☐ Applicant's name
- 2. ☐ Applicant's address
- 3. ☐ Title
- 4. ☐ Filing Date
- 5. ☐ Application Number
- 6. ☐ Foreign/PCT Application Re:
- 7. ☒ Other

Correct data

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7. 07/289,589 12/23/1988

In Domestic Priority Data,  
07/289,584 12/21/1988

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8a)

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

☐ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: \_\_\_\_\_

(type or print name of person certifying)

(Request for Corrected Filing Receipt [5-8]—page 1 of 2)

3. (complete the following applicable item)

A. ☐ The correction(s) is/are not due to any error by applicant and no fee is due.

OR

B. ☒ At least one of the above corrections is due to applicant's error and the fee therefor, under 37 C.F.R. § 1.19(h), of \$25.00 is paid as follows:

☐ Enclosed is check for \$25.00.

☒ Charge Account 07-1074 \$25.00.

  
SIGNATURE OF PRACTITIONER

Reg. No.: 31,310

Jennifer A. Tegfeldt

(type or print name of practitioner)

Tel. No.: (617) 374-7219

Genzyme Corporation

P.O. Address

One Kendall Square  
Cambridge, MA 02139

Customer No.:

(Request for Corrected Filing Receipt [5-8]—page 2 of 2)

#7

**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533)(Large Entity)**Docket No.  
GC22.4CON

In Re Application Of: Rasmussen et al.

Serial No.  
09/995,337Filing Date  
November 27, 2001Examiner  
Not Yet AssignedGroup Art Unit  
1652

Invention: ENZYMATICALLY ACTIVE RECOMBINANT GLUCOCEREBROSIDASE

TO THE ASSISTANT COMMISSIONER FOR PATENTS:Box Missing Parts

This is a response to the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533) mailed on  
December 17, 2001  
Date

Enclosed herewith for filing are the following:

- ☒ A copy of the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533). **(REQUIRED)**
- ☒ An oath or declaration in compliance with 37 CFR 1.63, including residence information and identifying the application by the above Application Number and Filing Date.
- ☐ A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date.
- ☐ An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date.
- ☐ A verified English translation of the non-English language application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the United States Patent and Trademark Office.
- ☒ Other (list):

Response to Notice to File Missing Parts of Nonprovisional Application  
Supplemental Preliminary Amendment  
Specification (34 pages)  
Abstract (1 page)  
Drawings (9 pages)  
American Type Culture Collection's Receipt Forms (2)  
Request for Corrected Filing Receipt

07/22/2002 RHEBRAHT 00000010 09995337  
03 FC:128 1960.00 CH

**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533)(Large Entity)**

Docket No.  
GC22.4CON

In Re Application Of: Rasmussen et al.

Serial No.  
09/995,337

Filing Date  
November 27, 2001

Examiner  
Not Yet Assigned

Group Art Unit  
1652

Invention: ENZYMATICALLY ACTIVE RECOMBINANT GLUCOCEREBROSIDASE

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Box Missing Parts

☒ Completion of application fees as calculated below:

☐ Utility application filing fee

☐ Design application filing fee

☐ Total number of independent claims = \_\_\_\_\_

☐ Total number of claims = \_\_\_\_\_

☐ Multiple dependent claims

☒ Surcharge for late payment of filing fee and/or late filing of original declaration or oath \$130.00

☐ Petition and fee for filing by other than all the inventors or a person not the inventor

☐ Fee for processing an application filed with a non-English language specification

☒ ~~Fee for processing and retention of application~~ **Fee for Request for Corrected Filing Receipt** \$25.00

Total completion of application fees \$155.00

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response to the above-identified Notice to File Missing Parts of Application. The requested extension is as follows (check time period desired). If an additional time extension is required, please consider this a petition therefor.

☐ One month ☐ Two months ☐ Three months ☐ Four months ☒ Five months

from: February 17, 2002 until: July 17, 2002  
Date Date

Total time extension fees \$1,960.00

Total fees due \$2,115.00



Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533) (Large Entity)

Docket No.  
GC22.4CON

In Re Application of Rasmussen et al.

Serial No.  
09/995,337

Filing Date  
November 27, 2001

Examiner  
Not Yet Assigned

Group Art Unit  
1652


Invention: ENZYMATICALLY ACTIVE RECOMBINANT GLUCOCEREBROSIDASE

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Box Missing Parts

The fee of \$2,115.00 is to be paid as follows:

- ☐ A check in the amount of the fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 07-1074  
A duplicate copy of this sheet is enclosed.
- ☒ If an additional extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. 07-1074  
A duplicate copy of this sheet is enclosed.

  
Signature  
Jennifer A. Tegfeldt, Reg. No. 31,310

Dated: July 16, 2002

I certify that this document and fee is being deposited on \_\_\_\_\_ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

CC:



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/995,337	11/27/2001	1652	740	GC22.4- CON	11	20	3

CONFIRMATION NO. 1762

## FILING RECEIPT



\*OC000000007204851\*

Jennifer A. Tegfeldt, Esq.  
GENZYME CORPORATION  
One Kendall Square  
Cambridge, MA 02139

Date Mailed: 12/17/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

## Applicant(s)

James Rasmussen, Boston, MA;  
Gary Barsomian, Georgetown, MA;  
Michel Bergh, Belmont, MA;

## Domestic Priority data as claimed by applicant

THIS APPLICATION IS A CON OF 08/442,603 05/17/1995  
WHICH IS A CON OF 08/015,735 02/10/1993 ABN  
WHICH IS A CON OF 07/748,283 08/21/1991 PAT 5,236,838  
WHICH IS A DIV OF 07/455,507 12/22/1989 ABN  
WHICH IS A CIP OF ~~07/289,584 12/21/1988 PAT D, 307,800 \*~~ **07/289,589 12/23/1988**  
(\*) Data inconsistent with PTO records.

## Foreign Applications

If Required, Foreign Filing License Granted 12/10/2001

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

**Title**

Enzymatically active recombinant glucocerebrosidase

**Preliminary Class**

435

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



Express Mail Label No. EV 093387704 US

#8

# American Type Culture Collection

**RECEIVED**

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)881-2600 Telex: 898-055 ATCCNORTH

JAN - 9 1989

**L. H. McCARTER**

The American Type Culture Collection (ATCC) has received your deposit of a culture in connection with the filing of an application for patent. The following information is provided to fulfill Patent Office requirements.

Name and Address of Depositor: Genzyme Corporation  
Attention: Michel L. E. Bergh  
75 Kneeland Street  
Boston, Massachusetts 02111

Deposited on Behalf of: Genzyme Corporation

Date of Receipt of Culture by the ATCC: December 22, 1988

<u>Scientific Description</u>	<u>Depositor's Reference</u>	<u>ATCC Designation</u>
<u>Escherichia coli</u> DHS alpha	pVL941.GCRD21	67866

The ATCC understands that:

1. The deposit of this culture does not grant to ATCC during the effective term of the patent anticipated, a license, either expressed or implied, to infringe the patent, and our release of this culture to others does not grant them a license, either expressed or implied, to infringe the patent.
2. If this culture should die or be destroyed during the effective life of the patent, it shall be your responsibility to replace it with a living culture of the same organism.

The ATCC agrees that in consideration for a one-time service charge, not to distribute this culture or any information relating thereto or to its deposit until such time as a patent has been issued disclosing the above deposit except in accordance with U.S. Patent Office Rule of Practice, Rule 14, or until you authorize us to make this strain available. After a patent is issued and we are so informed, the culture will be made available for distribution to the public. The ATCC agrees to maintain the culture for a period of 30 years from deposit date, or until at least five years after the most recent request for a sample, whichever is longer.

We further agree that the name and address of every requester shall be communicated to the depositor.

The culture was tested and was viable December 23, 1988.

Check in the amount of \$980.00 received. Thank you.

American Type Culture Collection

By Bobbie A. Brandon  
(Mrs.) Bobbie A. Brandon, Head  
ATCC Patent Depository

Date: December 27, 1988

cc: ✓ Lowell McCarter  
Richard Warburg



# American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)881-2600 Telex: 898-055 ATCCNORTH

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Gary Barsonian  
Genzyme  
One Kendall Square  
Cambridge, Massachusetts 02142

Deposited on Behalf of: Gary Barsonian

Identification Reference by Depositor:

ATCC Designation

Escherichia coli DH5alpha/pGB42

68194

The deposit was accompanied by:    a scientific description   X   a proposed taxonomic description indicated above.

The deposit was received December 21, 1989 by this International Depository Authority and has been accepted.

AT YOUR REQUEST:

  X   We will inform you of requests for the strain for 30 years.  
       We will not inform you of requests for the strain.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with a living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested December 26, 1989. On that date the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Bobbie A. Brandon

(Mrs.) Bobbie A. Brandon, Head, ATCC Patent Depository

Date: December 27, 1989